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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/030,960	10/25/2002	Catherine J. Pachuk	AM100062	2832

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EXAMINER

WOLLENBERGER, LOUIS V

ART UNIT PAPER NUMBER

1635

DATE MAILED: 08/29/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/030,960

Applicant(s)

PACHUK ET AL.

Examiner

Louis V. Wollenberger

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 January 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-54 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-54 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1–30 and 32, drawn to a double stranded polynucleotide molecule having a first coding strand and a second transcription template strand, and to a pharmaceutical composition thereof;

Group II, claim(s) 31 and 32, drawn to a double stranded polynucleotide molecule having wobble base modifications, and to a pharmaceutical composition thereof;

Group III, claims 33–35, drawn to a single stranded polynucleotide sequence selected from a first strand or second strand of a double stranded polynucleotide molecule, and to a pharmaceutical composition thereof;

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Group IV, claim(s) 36–45 and 47, drawn to a single stranded RNA molecule that is incapable of forming a double stranded or partially double stranded RNA molecule, and to a pharmaceutical composition thereof;

Group V, claim(s) 46, drawn to a single stranded RNA molecule having wobble base modifications;

Group VI, claim(s) 48–51 and 54, drawn to a method for enhancing the efficiency of expression of a polynucleotide sequence in a host cell, and to a method for treating a host subject, and to a method for preventing the inadvertent down regulation of a polynucleotide sequence in a host cell, using a double stranded polynucleotide molecule having a first coding strand and a second transcription template strand, or a pharmaceutical composition thereof;

Group VII, claim 51, drawn to a method for treating a host subject, using a pharmaceutical composition comprising a double stranded polynucleotide having wobble base modifications;

Group VIII, claims 52 and 53, drawn to a method for enhancing the efficiency of expression of a selected polynucleotide sequence, and to a method for treating a host subject, using a single stranded RNA molecule:

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Group IX, claim 54, drawn to a method for preventing inadvertent down regulation of a polynucleotide, comprising the use of a pharmaceutical composition containing a double stranded polynucleotide molecule having wobble base modifications;

Group X, claim 54, drawn to a method for preventing inadvertent down regulation of a polynucleotide, comprising the use of a pharmaceutical composition containing a single stranded RNA molecule that is incapable of forming a double stranded or partially double stranded RNA molecule;

The inventions listed as Groups I–X do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons.

The special technical feature of Groups I, II, VI, VII, and IX is a double stranded polynucleotide molecule. However, this cannot be a special technical feature under PCT Rule 13.2 because the element is known in the art. Villa-Komaroff et al. (1978, *Proc. Natl. Acad. Sci.* 75:3727–3731) disclose a double stranded cDNA clone of rat preproinsulin mRNA (see, for example, paragraph 3, page 3727). The clone was constructed in pBR322, transformed into *E. coli*, and expressed as a fusion polypeptide. The reference specifically suggests (page 3730) the use of such methods to express viral antigens, e.g., as possible vaccines.

The special technical feature of Groups III, IV, V, VIII, and X is a single stranded polynucleotide. However, this cannot be a special technical feature under PCT Rule 13.2 because

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the element is known in the art. U.S. Patent 5,130,238 teaches a process for using and synthesizing single stranded RNA (see document throughout).

Groups I, II, VI, VII, and IX do not share the same or corresponding technical feature as Groups III, IV, V, VIII, and X. The special technical feature of Groups I, II, VI, VII, and IX is a double stranded polynucleotide claimed therein, which is not present in Groups III, IV, V, VIII, and X.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Conclusion

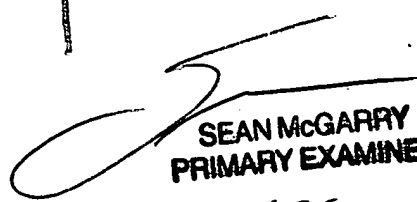
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Louis V. Wollenberger whose telephone number is 571-272-8144. The examiner can normally be reached on Mon–Fri, 8:00 am–4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's acting supervisor, Andrew Wang can be reached on 571-272-0811. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval system (PAIR). Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public. For more information about the PAIR system, see <http://pair-direct.uspto.gov>.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.


SEAN MCGARRY
PRIMARY EXAMINER
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Louis V. Wollenberger, Ph.D.

Examiner

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August 12, 2005

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